UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
WESTERN DIVISION

CINDY WILLIAMS,	)	
	)	
Plaintiff,	)	
vs.	)	CASE NO. 08-C-
	)	
DAVOL, INC. and	)	
C.R. BARD, INC.,	)	
Defendant.	)	

08 C 50191

JUDGE REINHARD
MAGISTRATE JUDGE MAHONEY

COMPLAINT

Plaintiff, CINDY WILLIAMS, by and through her attorneys, SHRIVER, O'NEILL & THOMPSON, by Joyce O'Neill Austin, states as follows:

PARTIES

1. Plaintiff, CINDY WILLIAMS is a citizen and resident of the City of Rockford, State of Illinois.

2. Defendant, DAVOL INC. ("DAVOL") is a corporation that is incorporated under the laws of the State of Rhode Island. DAVOL has its principal place of business in the State of Rhode Island. It manufactures the Composix® Kugel Mesh Patches ("Kugel Patch") at 100 Sockanosset Crossroad, Cranston, Rhode Island. DAVOL has a registered agent in Rhode Island at CT Corporation System, 10 Weybosset St., Providence, Rhode Island. DAVOL focuses its business on products in key surgical specialties, including hernia repair, hemostasis, orthopedics, and laparoscopy.

3. Defendant, C. R. BARD INC. ("BARD") is a corporation that is incorporated under the laws of the State of New Jersey. It is the corporate parent/stockholder of DAVOL and

participates in the manufacture and distribution of the Kugel Patch. It also manufactures and supplies DAVOL with material that forms part of the Kugel Patch. BARD at all times relevant did substantial and continuous business in the State of Illinois by placing the product into the stream of commerce.

JURISDICTION

4. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(d) because the parties are citizens of different States and the matter in controversy exceeds the jurisdictional amount exclusive of interest and costs.

5. Venue is proper in the Northern District of Illinois under 28 U.S.C. §1391.

6. This action includes claims for injuries to Plaintiff caused by the insertion of Composix Kugel Mesh and therefore should be, and Plaintiff consents to, transfer to **Multidistrict Litigation No. 1842 In Re: Kugel Mesh Hernia Patch Products Liability Litigation,** United States District Court, District of Rhode Island, the Honorable Mary M. Lisi.

FACTS

7. Defendant DAVOL designed, manufactured and distributed the Composix Kugel Patch, a hernia mesh patch that was inserted into Plaintiff's body to repair a hernia on September 1, 2006.

8. Defendant DAVOL, through its agents, servants and employees, participated in the manufacture and delivery of the Composix Kugel Patch that was inserted into Plaintiff's body.

9. The Defendants submitted their 510k Application to the Federal Drug Administration (hereinafter referred to as the "FDA") on January 22, 2001. Following this 510k Application the Composix Kugel Patch was authorized by the FDA as a Class II medical device.

10. Immediately after the Kugel Patches were placed on the market, DAVOL and BARD began receiving actual notices of memory ring failures and Kugel Patch defects. DAVOL and BARD actively and intentionally concealed this notice of the defective and dangerous condition associated with the Kugel Patches from Plaintiff, Plaintiff's physicians, and the general public.

11. After the defective and dangerous Kugel Patch was already placed on the market, Defendants DAVOL and BARD conducted physician screenings and reviews as early as 2002. An Establishment Inspection Report ("EIR") conducted by the FDA in 2006 found that the post market survey validation process of the device was incomplete and failed to include all the data from the physicians surveyed during this time. Whether intentionally or negligently, BARD and DAVOL failed to properly conduct and monitor their own post market design validation physician surveys including those which demonstrated unfavorable or "dissatisfied" results. These complaints and concerns of the physician surveyors were actively concealed by DAVOL and BARD from Plaintiff, Plaintiff's surgeons, and the public at large.

12. The Composix Kugel Patch hernia repair product implanted in the Plaintiff was designed, manufactured, sold and distributed by DAVOL to be used by surgeons for hernia repair surgeries and was further represented by DAVOL to be an appropriate, cost-effective and suitable product for such purpose.

13. No later than September 2004, Defendants uncovered serious problems with the weld process involving the memory recoil ring. Despite attempts to correct the problem at the plant, BARD and DAVOL found the corrective measures to be ineffective and the process still not in control. DAVOL and BARD were aware these weld issues had existed from the time the Kugel Patches were originally placed on the market and all current lots suffered from this dangerous defect. This information was intentionally withheld at this time from the Plaintiff, Plaintiff's physicians, the

FDA, and all other individuals who had been implanted or would be implanted with Kugel Patches using the memory recoil ring.

14. During the 2006 EIR, corporate executives informed the FDA that the spring and summer period of 2005 showed a marked increase in the number of complaints with the Kugel Patch and the memory recoil ring. In spite of their knowledge of increasing complaints and complications, DAVOL and BARD waited until August 30, 2005 to initiate a partial Kugel Patch distribution hold. DAVOL and BARD actively and intentionally chose not to immediately inform the Plaintiff, Plaintiff's physicians, the FDA, and all other individuals who had been implanted or would be implanted with Kugel Patches using the memory recoil ring. DAVOL and BARD waited until December 2005 to notify the public of the potential severity of the complications which were resulting from the dangerous and defective Kugel Patches and have since admitted that the product quality hold and release procedure was not applied on a timely basis.

15. An FDA Class I recall is issued for problems related to medical devices that are potentially life-threatening or could cause a serious risk to the health of the patients implanted with the devices.

16. On December 22, 2005, DAVOL recalled many sizes of Composix Kugel Patches under a Class I recall notice.

17. The Composix Kugel Patch was recalled due to a faulty "memory recoil ring" that can break under pressure. Incidents of ring migration, intestinal fistulae, bowel perforation and even death have been reported.

18. The FDA conducted the aforementioned EIR investigations in January and February of 2006. The results of these investigations determined, among other things, that BARD and DAVOL:

i. had excluded ring failure events which should have been included from their complication database, reports, and recall notices;
ii. misidentified numerous Kugel Patch complication events;
iii. failed to apply the product quality hold and release procedure on a timely basis;
iv. failed to properly follow the procedures for conducting design validation review;
v. failed to identify all the actions necessary to correct and prevent the recurrence of further ring break and Kugel Patch complications; specifically, they provided no justification for including only the Extra Large Kugel Patch sizes in the December 2005 recall;
vi. failed to provide full information which they knew regarding numerous Kugel Patch complaints;
vii. failed to actually perform strength testing on memory recoil rings for all sizes of Kugel patch before putting them into the stream of commerce;
viii. failed to maintain appropriate sources for quality data to identify, track, and trend existing and potential causes for the ring failures and Kugel Patch complaints resulting in numerous inconsistencies and errors in the raw data and from the actual complaints and what was placed in the electronic databases.

19. On March 24, 2006, the initial Class I recall on the Composix Kugel Patch was expanded to include several more sizes of the patch and numerous additional lots of the defective hernia mesh product.

20. On January 10, 2007, the existing recall on the Composix Kugel Patch was again expanded to encompass further production lots of the defective hernia mesh product.

21. Plaintiff was never informed by Defendants of the defective, dangerous, and recalled nature of the Kugel Patch and memory recoil ring which had been implanted until well after discovery of Bard's and Davol's FDA recall of the product.

22. Neither Plaintiff nor Plaintiff's physicians were aware of the defective and dangerous condition of the Kugel Patch or that this unreasonably defective condition was the cause of Plaintiff's injuries until some time after BARD and DAVOL chose to finally inform the general public of the defective nature of the Kugel Patches and the subsequent recalls.

23. DAVOL and BARD withdrew a large number of Composix Kugel Patches as a result of the high complication and failure rate of the product.

24. Upon information and belief DAVOL and BARD failed to comply with the FDA application and reporting requirements.

25. Upon information and belief DAVOL and BARD were aware of the high degree of complication and failure rate associated with their Composix Kugel Patch before it was recalled.

26. Upon information and belief DAVOL and BARD were aware of the defect in manufacture and design prior to the recall of their Kugel Patch.

27. Upon information and belief, the complications and failures associated with the Composix Kugel Patches are not limited to the sizes which DAVOL and BARD has already recalled.

28. Upon information and belief, DAVOL and BARD were aware of the defect in manufacture and design of the non-recalled Kugel Composix Patch sizes and chose not to issue a recall on all Kugel Composix Patches in the face of the high degree of complication and failure rates.

29. On September 1, 2006, Plaintiff had an umbilical hernia repair performed at OSF Saint Anthony's Hospital in Rockford, Illinois. Plaintiff had a Composix Kugel Patch implanted during this procedure.

30. This Composix Kugel Patch was removed on August 15, 2008, at OSF Saint Anthony's Hospital in Rockford, Illinois, and was found to be "balled up" from a size of 9cm to 3-4cm in diameter.

31. The Plaintiff has suffered and will continue to suffer physical pain and mental anguish as a direct and proximate use of the defective and dangerous Composix Kugel Patch and its resulting failure in that she had temporary kidney failure and fluid build up and thirteen (13) visits to the emergency room complaining of severe abdominal pain.

32. The Plaintiff has incurred substantial medical bills and the Plaintiff has suffered loss of other monies and wages as a direct and proximate use of the Composix Kugel Patch and its resulting failure.

COUNT I
Negligence

33. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the preceding paragraphs as though fully set forth herein.

34. Defendants DAVOL and BARD were negligent to Plaintiff in the following respects:

35. DAVOL and BARD at all times mentioned had a duty to properly manufacture, test, inspect, package, label, distribute, market, examine, maintain, supply, provide proper warnings and prepare for use the Composix Kugel Patch.

36. DAVOL and BARD at all times mentioned knew or in the exercise of reasonable care should have known, that the Composix Kugel Patches were of such a nature that they were not properly manufactured, tested, inspected, packaged, labeled, distributed, marketed, examined, sold supplied, prepared and/or provided with the proper warnings, and were unreasonably likely to injure the Composix Kugel Patch's users.

37. DAVOL and BARD so negligently and carelessly designed, manufactured, tested, failed to test, inspected, failed to inspect, packaged, labeled, distributed, recommended, displayed, sold, examined, failed to examine and supplied the Composix Kugel Patch, that they were dangerous and unsafe for the use and purpose for which it was intended.

38. DAVOL and BARD were aware of the probable consequences of the Composix Kugel Patch. DAVOL and BARD knew or should have known the Composix Kugel Patch would cause serious injury; they failed to disclose the known or knowable risks associated with the

Composix Kugel Patch. DAVOL and BARD willfully and deliberately failed to avoid those consequences, and in doing so, DAVOL and BARD acted in conscious disregard of the safety of the Plaintiff.

39. Defendants DAVOL and BARD owed a duty to the Plaintiff to adequately warn her and her treating physicians, of the risks of breakage, separation, tearing and splitting associated with the Composix Kugel Patch and the resulting harm and risk it would cause patients.

40. Defendants DAVOL and BARD breached their duty by failing to comply with state and federal regulations concerning the study, testing, design, development, manufacture, inspection, production, advertisement, marketing, promotion, distribution, and/or sale of the Composix Kugel Patch.

41. As a direct and proximate result of the duties breached, the Composix Kugel Patch used in the Plaintiff hernia repair surgery failed, resulting in the Plaintiff suffering pain and harm.

42. As a direct and proximate result of DAVOL's and BARD's negligence, the Plaintiff has suffered injuries and damages, some of which are permanent in nature.

43. DAVOL's and BARD's conduct in continuing to market, sell and distribute the Composix Kugel Patch after obtaining knowledge they were failing and not performing as represented and intended, showed complete indifference to or a conscious disregard for the safety of others justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter DAVOL, BARD and others from similar conduct in the future.

Wherefore, Plaintiff requests a judgment against DAVOL and BARD for damages in a sum to confer jurisdiction upon this Court together with interest on that amount at the legal rate from the date of judgment until paid, for court costs and for other such relief this Court deems just and appropriate.

COUNT II
Strict Product Liability

44. Plaintiff re-alleges and incorporates by reference each and every allegation contained in preceding paragraphs as though fully set forth herein.

45. Defendants DAVOL and BARD are strictly liable to Plaintiff in the following respects:

46. DAVOL and BARD designed, manufactured, assembled, distributed, conveyed and/or sold the Kugel Patch for hernia repair surgery.

47. The Composix Kugel Patches subject to the Class I recall were defective because they failed to perform safe and effectively for the purpose they were originally designed. The Plaintiff's Composix Kugel Patch was a Class I recalled device that failed while in her body causing her to develop serious physical complications which required subsequent, painful and unnecessary removal surgery of her Composix Kugel Patch.

48. At all times mentioned, the Composix Kugel Patch was substantially in the same condition as when it left the possession of DAVOL.

49. The Composix Kugel Patch implanted into the Plaintiff was being used in a manner reasonably anticipated at the time it was implanted in her by her surgeon to repair her hernia.

50. The Composix Kugel Patches, like the one found in the Plaintiff at the time they left the possession of DAVOL and BARD were inherently dangerous for their intended use and were unreasonably dangerous products which presented and constituted an unreasonable risk of danger and injury to the Plaintiff as follows:

i. The Composix Kugel Patch was sold in a defective condition by design and manufacture;
ii. The Composix Kugel Patch as designed and manufactured was unsafe to the Plaintiff;

iii. The Composix Kugel Patch as designed and manufactured was unreasonably dangerous to the Plaintiff;

iv. The Composix Kugel Patch did not perform safely as an ordinary consumer/patient, like the Plaintiff, would expect;

v. The Composix Kugel Patch as designed and manufactured was unsafe for its intended use;

vi. DAVOL and BARD failed to warn the end user about the dangers and risks of the product;

vii. DAVOL and BARD knew the component parts of the Composix Kugel Patch as implemented through design and/or manufacture could cause injury to the end user;

viii. Failing to implement an adequate, safe and effective "memory recoil ring" and/or its interaction with the mesh of the Composix Kugel Patch to withstand the foreseeable stresses they would be subject to within the intra-abdominal space;

ix. Failing to avoid migration of the Composix Kugel Patch and/or its components from the initial site of the hernia repair surgery.

x. Any other acts or failures to act by DAVOL or BARD regarding the studying, testing, designing, developing, manufacturing, inspecting, producing, advertising, marketing, promoting, distributing, and/or sale of Composix Kugel Patches for hernia repair surgery as will be learned during discovery.

51. DAVOL's and BARD's conduct in continuing to market, sell and distribute the Composix Kugel Patch after obtaining knowledge they were failing and not performing as represented and intended, showed complete indifference to or a conscious disregard for the safety of others justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter DAVOL, BARD and others from similar conduct in the future.

Wherefore, Plaintiff requests a judgment against DAVOL and BARD for damages in a sum as permitted by statute together with interest on that amount at the legal rate from the date of judgment until paid, for court costs and for other such relief this Court deems just and appropriate.

COUNT III
Negligent Infliction of Emotional Distress

52. Plaintiff re-alleges and incorporates by reference each and every allegation contained in preceding paragraphs as though fully set forth herein.

53. Defendants DAVOL and BARD are liable to Plaintiff for the negligent infliction of emotional distress in the following respect:

54. The Plaintiff suffered severe emotional distress, which was as a result of Defendant's negligent conduct in studying, designing, developing, testing, inspecting, manufacturing, producing, advertising, marketing, promoting, distributing, and/or selling of the Composix Kugel Patch for hernia repair surgery.

55. The Plaintiff suffered severe emotional distress, which was as a result of DAVOL's and BARD's negligent conduct in failing to adequately and safely design and construct an effective and safe Composix Kugel Patch for hernia repair surgery.

56. Therefore, DAVOL and BARD are liable to Plaintiff.

57. DAVOL's and BARD's conduct in continuing to market, sell and distribute the Composix Kugel Patch after obtaining knowledge they were failing and not performing as represented and intended, showed complete indifference to or a conscious disregard for the safety of others justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter DAVOL, BARD and others from similar conduct in the future.

Wherefore, Plaintiff requests a judgment against DAVOL and BARD for damages in a sum to confer jurisdiction upon this Court together with interest on that amount at the legal rate from the date of judgment until paid, for court costs and for other such relief this Court deems just and appropriate.

COUNT IV
Intentional Infliction of Emotional Distress

58. Plaintiff re-alleges and incorporates by reference each and every allegation contained in preceding paragraphs as though fully set forth herein.

59. Defendants DAVOL and BARD are liable to Plaintiff for the intentional infliction of emotional distress in the following respect:

60. The Plaintiff suffered severe emotional distress, which was as a result of DAVOL's and BARD's extreme outrageous, intentional, willful, and reckless conduct in studying, designing, developing, testing, inspecting, manufacturing, producing, advertising, marketing, promoting, distributing, and/or sale of the Composix Kugel Patch for hernia repair surgery.

61. The Plaintiff suffered severe emotional distress, which was as a result of DAVOL's and BARD's extreme outrageous, intentional, willful, and reckless conduct in failing to adequately and safely design and construct an effective and safe Composix Kugel Patch for hernia repair surgery, in complete and reckless disregard of safety to the Plaintiff.

62. Therefore, DAVOL and BARD are liable to Plaintiff.

63. DAVOL's and BARD's conduct in continuing to market, sell and distribute the Composix Kugel Patch after obtaining knowledge they were failing and not performing as represented and intended, showed complete indifference to or a conscious disregard for the safety of others justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter DAVOL, BARD and others from similar conduct in the future.

Wherefore, Plaintiff requests a judgment against DAVOL and BARD for damages in a sum to confer jurisdiction upon this Court together with interest on that amount at the legal rate from the date of judgment until paid, for court costs and for other such relief this Court deems just and appropriate.

COUNT V
Breach of Implied Warranty

64. Plaintiff re-alleges and incorporates by reference each and every allegation contained in preceding paragraphs as though fully set forth herein.

65. Defendants DAVOL and BARD are liable to Plaintiffs for their breach of implied warranty in the following respect:

66. DAVOL and BARD sold the Kugel Patch which was implanted in the Plaintiff, DAVOL and BARD impliedly warranted to the Plaintiff, her physicians and health care providers, that the Composix Kugel Patch was of merchantable quality and safe for the use for which they were intended.

67. DAVOL and BARD knew or should have known that the Composix Kugel Patch at the time of sale was intended to be used for the purpose of surgically implanting them into the body for hernia repair.

68. The Plaintiff, her physicians and health care providers reasonably relied on DAVOL's and BARD's judgment, indications and statements that the Composix Kugel Patch was fit for such use.

69. When the Composix Kugel Patches was distributed into the stream of commerce and sold by DAVOL and BARD, they were unsafe for their intended use, and not of merchantable quality, as warranted by DAVOL and BARD in that they had very dangerous propensities when used as intended and implanted into a patient's body where they could cause serious injury of harm or death to the end user.

70. The Plaintiff suffered such injuries and damages as a result of DAVOL and BARD's conduct and actions.

COUNT VI
Failure to Warn

71. Plaintiff re-alleges and incorporates by reference each and every allegation contained in preceding paragraphs as though fully set forth herein.

72. In the course of business, DAVOL and BARD designed, manufactured and sold the Composix Kugel Patch to OSF Saint Anthony's Hospital for hernia repair surgeries.

73. At the time of the design, manufacture and sale of the Composix Kugel Patch, and more specifically at the time the Plaintiff received the Composix Kugel Patch, they were defective and unreasonably dangerous when put to their intended and reasonably anticipated use. Further the Composix Kugel Patches were not accompanied by proper warnings regarding significant adverse consequences associated with the Composix Kugel Patch.

74. BARD and DAVOL failed to provide any warnings, labels or instructions of its dangerous propensities that were known or reasonably scientifically knowable at the time of distribution. The reasonably foreseeable use of the products involved significant dangers not readily obvious to the ordinary user of the products. BARD and DAVOL failed to warn of the known or knowable injuries associated with malfunction of the Composix Kugel Patch, including but not limited to rupture of the Patch and resulting intermit trauma and infection which would require subsequent surgical procedures and could result in severe injuries.

75. The dangerous and defective conditions in the Composix Kugel Patches existed at the time they were delivered by the manufacturer to the distributor. At the time the Plaintiff had her hernia repair surgery the Composix Kugel Patch was in the same condition as when manufactured, distributed and sold.

76. The Plaintiff did not know at the time of use of the Composix Kugel Patch, not at any time prior thereto, of the existence of the defects in the Patches.

77. The Plaintiff suffered the aforementioned injuries and damages as a direct result of DAVOL and BARD's failure to warn.

78. The conduct of BARD and DAVOL in continuing to market, promote, sell and distribute the Composix Kugel Patch after obtaining knowledge that the products were failing and not performing as represented and intended, showed a complete indifference to or conscious disregard for the safety of others justifying an award in such sum which will serve to deter BARD, DAVOL and others from similar conduct.

COUNT VII
Fraud

79. Plaintiff re-alleges and incorporates by reference each and every allegation contained in preceding paragraphs as though fully set forth herein.

80. In the course of business, DAVOL and BARD designed, manufactured and sold the Composix Kugel Patch for hernia repair surgeries.

81. At the time of the design, manufacture and sale of the Composix Kugel Patch, and more specifically at the time the Plaintiff received the Composix Kugel Patch, they were defective and unreasonably dangerous when put to their intended and reasonably anticipated use. Further the Composix Kugel Patches were not accompanied by proper warnings regarding significant adverse consequences associated with the Composix Kugel Patch.

82. BARD and DAVOL was aware of the dangerous and defective condition of the products and intentionally withheld this information from the Plaintiff, Plaintiff's physicians, and the general public even though these significant dangers were not readily obvious to the ordinary user of the products, even after a post surgical complication had arisen.

83. BARD and DAVOL fraudulently presented to the Plaintiff, Plaintiff's physicians, and the general public that the Kugel Patch was a safe and effective product while they were fully aware that the dangerous and defective nature of the Kugel could and would cause injuries such as those suffered by Plaintiff.

84. The Plaintiff and Plaintiff's physicians relied upon the fraudulent misrepresentations and concealments of Defendants and allowed for the defective Kugel Patch to be implanted in Plaintiff.

85. As a direct and proximate result of the Plaintiff's reliance on BARD's and DAVOL's fraudulent misrepresentations and concealments, the Plaintiff was seriously and permanently injured.

86. The conduct of BARD and DAVOL in continuing to fraudulently market, promote, sell and distribute the Composix Kugel Patch while fraudulently concealing knowledge that the products were failing and not performing as represented and intended, showed a complete indifference to or conscious disregard for the safety of others justifying an award in such sum which will serve to deter BARD, DAVOL and others from similar conduct.

WHEREFORE, Plaintiff demands judgment against Defendants, jointly and severally:

a. Compensatory damages against Defendant on Causes of Action One, Two, Three, Four, Five, Six and Seven each in the amount of TWENTY MILLION ($20,000,000.00) DOLLARS;

b. Punitive damages against Defendant on Causes of Action One, Two, Three, Four and Seven each in the amount of TWENTY MILLION ($20,000,000.00) DOLLARS;

c. All together with interest, costs and disbursements;

d. Such other and further relief as this Court deems just and proper.

PLAINTIFFS REQUESTS A TRIAL BY JURY ON ALL COUNTS.

CINDY WILLIAMS, Plaintiff
By her Attorney,

/s/ Joyce O'Neill Austin
Attorney Joyce O'Neill Austin

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